ST. LIDETA COLLEGE

DEPARTMENT OF PHARMACY

Immunological and Biological Products

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- Course Description
  - **Module title:**
  - Immunological and Biological Products
  - **Module code:**
  - PHAR 413
  - **Credit value of the module:**
  - cr. Hours
- **Prerequisite:**
  - -Microbiology,
  - -Immunology and Parasitology

Methods of teaching

- Illustrated and interactive lecture using imaginative slides.
- Collaborative learning through brainstorming, question and answer, and group discussion
- Individual and group assignment
- Classroom presentation and discussion

Methods of teaching

- ✓ **Lectures**
- ✓ **Exercises/**
- ✓ **Assignments**

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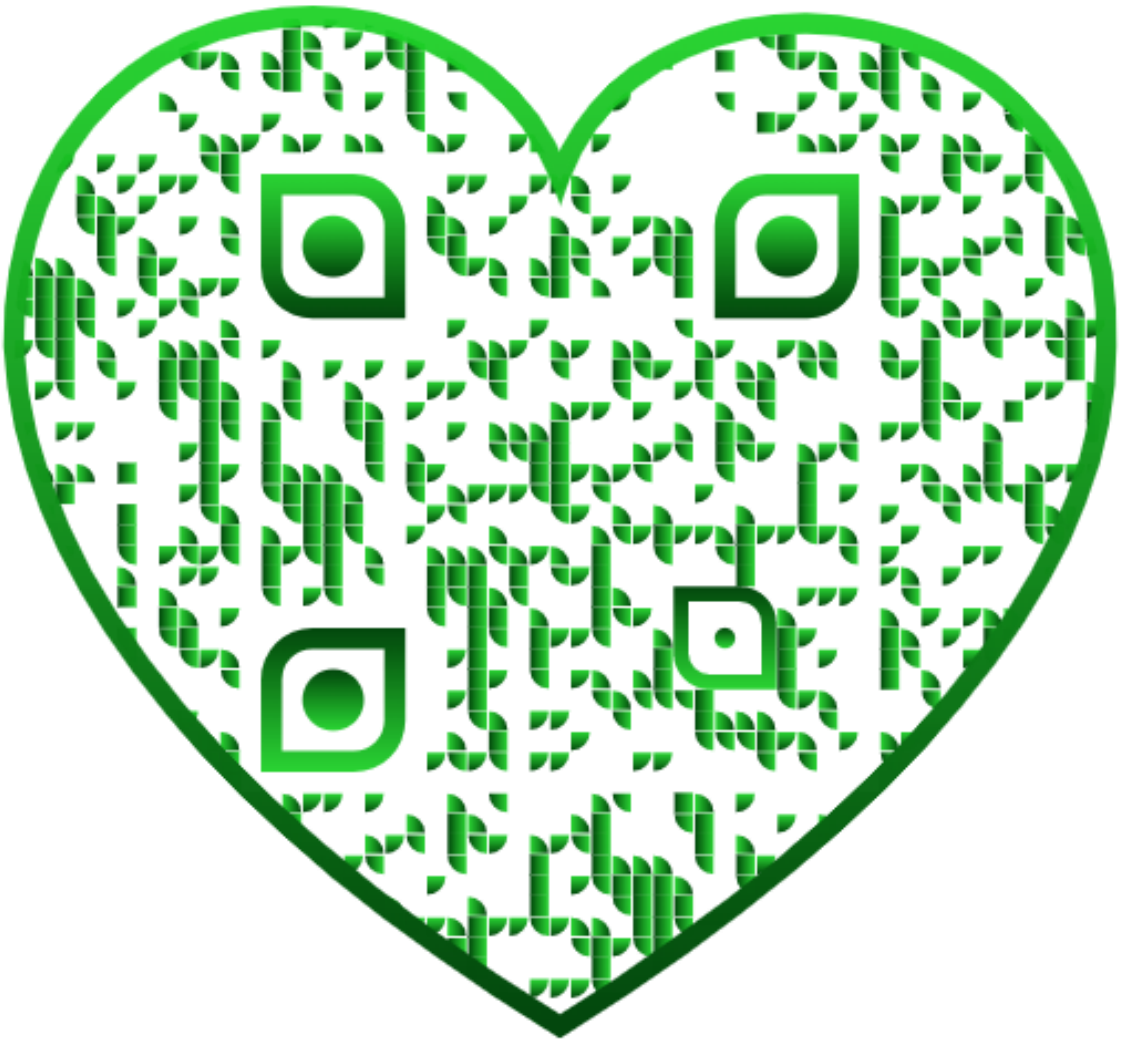

Course objective:

- After completing this course, the student will be able to explain the application of biotechnology in drug discovery and development.
- Discuss the role of genetic engineering and allied technologies that have underpinned the development of a range of pharmaceutical products of modern biotechnology that can be used in the pharmaceutical care of a patient.

What is Biotechnology?

- Biotechnology is the manipulation of living organisms and organic material to serve human needs.
- Examples:
  - Yeast in bread making and alcohol production
  - Use of beneficial bacteria (penicillin) to kill harmful organisms
  - Cloning of plants and animals
  - Artificial insemination

At the end of the course the student will be able to:

- Discuss the application of recombinant DNA derived drugs (immunological and biological products) in pharmaceutical care of a patient.
- Explain the handling of immunological and biological products
- Explain different therapeutic approaches such as gene therapy, antisense therapy, cell therapy
- Describe the immunological principles (immunotechnology) that are used in prevention and diagnosis of diseases.

- According to United Nations Convention on Biological Diversity :
  - **"Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."**

- United States Congress's Office of Technology Assessment defined biotechnology as
  - **"any technique that used living organism to make or modify a product, to improve plants or animals or to develop microorganisms for specific uses".**

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Definition cont'd…..

- Biologic processes of interest include cellular activities such as
  - Protein synthesis
  - DNA replication & transcription
  - Protein processing
  - Receptor-ligand interactions
  - Fermentation of bacteria, yeast, and mammalian cells.

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Biotechnology Industry

- Research is conducted by small companies, large corporations, and public universities.

Goal of biotechnology

- To understand more about the processes of inheritance and gene expression
- To provide **better** understanding & treatment of various diseases, particularly genetic disorders
- To **generate economic benefits**, including
  - improved plants & animals for agriculture
  - efficient production of valuable biological molecules

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Biotechnology Industry

- Funding comes from a variety of sources:
  - Public (government)
  - Private (companies and foundations)
- California passed a $300 billion referendum for research in stem cells in 2004.

Biotechnology Industry

- Focuses on a variety of research areas including:
  - Health/medicine
  - Food science
  - Environmental science
  - Agriscience

Impact of Biotechnology

- Genetically modified crops were produced on more than 167 million acres in 18 countries in 2003, a 15% increase from 2002
  - The US was the largest single producer with **more than 60% of the total** acreage in production.

Impact of Biotechnology

- Genetically modified organisms (GMOs) are consumed by millions of people EVERY DAY.
  - Almost 56% of all soybean plantings worldwide are genetically engineered (much higher in the US)

Impact of Biotechnology

- The national Biotechnology Center predicts that the biotechnology industry in the state will contribute more than **$25 billion in annual income** each year within the next 25 years.

Pioneers in Biotechnology

Gregor Mendel

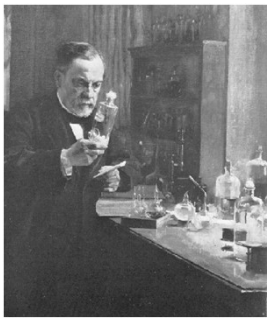
- 1863
- **Austrian monk** who conducted the first genetics experiments using pea plants in the mid 1800s.
- Often considered the **founder of genetics**.

Gregor Mendel

Antony van Leeuwenhoek

- 1675
- **Discovered bacteria** using a simple microscope

Louis Pasteur



- 1870's
- Disproved the notion of spontaneous generation, describing the role of bacteria in spoilage and the scientific basis for fermentation
- Created the rabies vaccine

Robert Hooke

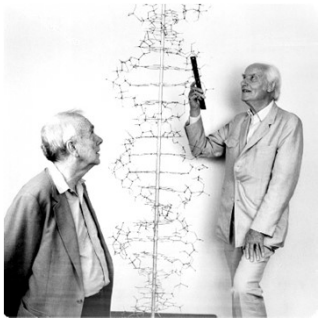
- 1665
- Invented the **compound light microscope**
- First to observe cells in cork

Paul Berg

- 1972
- Stanford University scientist who first developed recombinant DNA technology, a method for insertion of genetic material from one organism into another.

James Watson & Francis Crick

- 1953
- Englishmen responsible for the **discovery of the double helix structure of DNA** using X-ray photographs



Historical Development of Biotechnology

Historical…

- Ancient biotechnology relied on fermentation, the breakdown of organic molecules by MOs, particularly sugars, into simpler compounds, often carbon dioxide.

1869

- **DNA is discovered** in trout sperm by Swiss Miescher.

1750 B.C.

- Origins of "biotechnology" emerge in methods of food production and plant and animal breeding
  - Use of bacteria to produce cheese
  - Use of natural enzymes in yogurt
  - Use of yeast to produce bread
  - Use of fermentation for producing wine and beer

1919

- The word "biotechnology" is first used by a Hungarian agricultural engineer.

1940's-1950's

- Widespread work is undertaken **to investigate the structure and function of DNA**

1980's-1990's

- A variety of genetically modified organism's and biotechnology **techniques are introduced** in fields from agriculture to medicine
  - **Recombinant DNA technology**-extracts DNA from one organism for use in another, allowing more **rapid and specific improvements in plants and animals**
  - **Plant Tissue Culture-** gains widespread acceptance as **a method to quickly and cheaply produce genetically identical plants.**

1980

- The **U.S. Supreme Court approves** the patenting of genetically altered organisms.

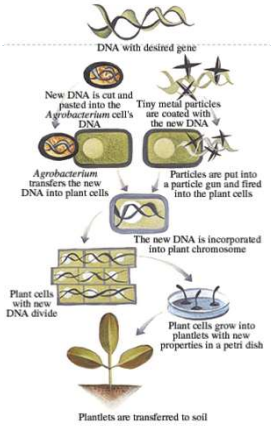
1997

- Dolly is the first animal cloned from diploid cells is produced in Scotland

Biotechnology and Agriscience

Plant Science

- Wide scale production of transgenic plants impacting horticulture

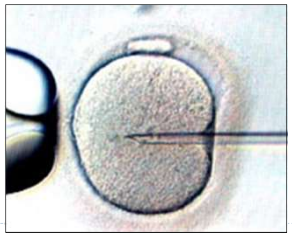

DNA with desired gene
New DNA is cut and pasted into the Agrobacterium cell's DNA
Tiny metal particles are coated with the new DNA
Agrobacterium transfers the new DNA into plant cells
Particles are put into a particle gun and fired into the plant cells
The new DNA is incorporated into plant chromosome
Plant cells with new DNA divide
Plant cells grow into plantlets with new properties in a petri dish
Plantlets are transferred to soil

Biotechnology and Agriscience

- There has been increased activity and research between different agricultural areas with common research techniques and goals
  - Plant Science
  - Animal Science
  - Environmental Science
  - Health/Agri-Medicine

Animal Science

- Increased use of methods of **in vitro fertilization** and **artificial insemination** improve selected breed programs



Environmental Science

- Use of biotechnology techniques in environmental science **for cleaning contaminants and protecting endangered species**
  - **Bioremediation-** use of natural organisms to clean contaminants

Health/Agri-medicine

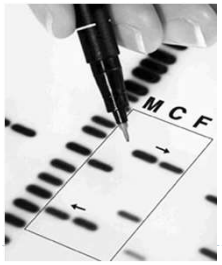
- **Pharming-** the creation of plants and animals capable of producing medical substances
- The use of biological barriers to prevent the spread of harmful microorganisms that could contaminate food sources

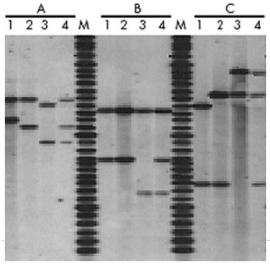
Environmental Science

- Immunoassay tests are used to test for the presence of contaminants in soil, water and even blood

Health/Agri-medicine

- **DNA analysis/paternity testing** has emerged as a technique to test the genetic ancestry of animals





Problems with Biotechnology in Agriculture

Problems with Biotechnology

- **Expense** of the utilization of many biotechnology techniques
  - Cost of producing transgenic animals (There are transgenic fish, but no livestock yet.)

Problems with Biotechnology

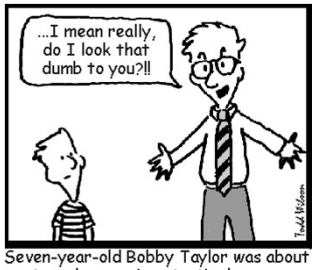
- Transfer of genes found in transgenic organisms to natural populations.- change to cancerous cells.
  - **Terminator genes** have been used to minimize this risk

Problems with Biotechnology

- Concerns over the **safety and ethics of incorporating** GMO's into food for human consumption
  - Allergens

Problems with Biotechnology

- **Lack of education** among both consumers and producers concerning biotechnology processes and products



Seven-year-old Bobby Taylor was about to make a serious tactical error.

Biotechnology Terms

- Use your biotechnology books to define the following terms:
  - Cloning
  - Clonal Offspring
  - Deoxyribonucleic acid
  - Genetics
  - Genetic Engineering
  - GMO
  - Ribonucleic Acid